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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,476	02/23/2004	Alan R. Fritzberg	295.044US3	1730

21186 7590 10/04/2005

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EXAMINER
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JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/784,476	FRITZBERG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005 and 07 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 52,53,80,81 and 86-95 is/are pending in the application.
- 4a) Of the above claim(s) 52,53,80 and 81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86-95 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## ACKNOWLEDGMENTS

1. The Examiner acknowledges the amendment filed 6/7/04 wherein claims 1-51, 54-79, 82-85 are canceled; claim 81 is amended; and claims 86-95 are added.

**Note:** Claims 52, 53, 80, 81, and 86-95 are pending.

## RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group III (claims 86-95) filed 7/15/05 is acknowledged. The traversal is on the grounds that that the claims are closely related and cannot be considered to be independent and distinct as evidence by their identical classification. Thus, it is not a burden on the Examiner to search the full scope of the claims. This is found non-persuasive because while the inventions classify in the same area, they are separate and distinct. For example, prior art directed to a method of treating osteomyelitis, infection of bone affecting the metaphysical regions of long bones, would not render obvious a hematopoietic genetic defect such as sickle cell anemia because sickle cell anemia involves the red blood cells whereas an infection of the bones (i.e., osteomyelitis) generally involves the white blood cells (e.g., leukemia). Thus, prior art that reads on osteomyelitis would neither anticipate nor render obvious sickle cell anemia. Hence, a separate search of the prior art is necessary and would be burdensome to the Examiner. Therefore, the restriction requirement is still deemed proper and is therefore made FINAL.

**Note:** The Examiner acknowledges Applicant's election of the species 166Ho-DOTMP. Initially, Applicant's elected species was searched in a method of treating

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osteomyelitis. However, since no prior art was found to render obvious or anticipate the elected invention, the search was expanded over the full scope of Group III.

### **WITHDRAWN CLAIMS**

3. Claims 52, 53, 80, and 81 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### **DOUBLE PATENTING REJECTIONS**

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 86-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 50-54, 60, 61, and 63 of copending Application No. 10/615,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a bone condition by administering a ligand complexed with a radionuclide. The claims of 10/615,484 encompass those of the instant invention. The claims differ in that those of 10/615,484 encompass other conditions other than osteomyelitis. However, a skilled practitioner in the art would recognize that osteomyelitis is a bone condition encompassed by 10/615,484 because the copending application specifically lists osteomyelitis as one of the conditions being treated in claim 61.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 86-95 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50, 51, 54, and 55 of copending Application No. 10/882,054. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a method of treating a bone condition by administering a ligand

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complexed with a radionuclide. The claims of 10/882,054 encompass those of the instant invention. The claims differ in that those of 10/882,054 encompass other conditions other than osteomyelitis. However, a skilled practitioner in the art would recognize that osteomyelitis is a bone condition encompassed by 10/882,054 because the copending application specifically lists osteomyelitis as one of the conditions being treated in claim 51.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### **COMMENTS/NOTES**

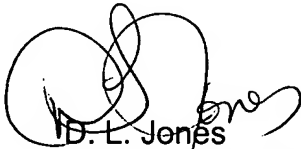
7. It should be noted that no prior art has been cited against Applicant's elected invention. However, Applicant MUST address and overcome the double patenting and 112 rejections above. In particular, the claims are free of the prior art of record because the prior art neither anticipates nor renders obvious a method of treating osteomyelitis by administering a ligand complexed radionuclide to a subject as set forth in independent claim 86. Applicant is reminded that the search was not expanded beyond elected Group III.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

September 30, 2005